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K010906
p. 1052

510(k) Summary of Substantial Equivalence

Proprietary Name:	Stylet Kit Models 6254, 6282, and 6293
Common Name:	Stylet
Device Classification:	Class II
Product Classification and Code:	Stylet, Catheter (74 DRB)
Classification Panel:	Circulatory System Devices Panel
Establishment Registration Number:	2182208
Contact Person:	Karen Clement Product Regulation Manager Medtronic, Inc. 4000 Lexington Avenue North Mail Stop: X260 Shoreview, MN 55126-2983 Telephone: (612) 514-9933 Facsimile: (612) 514-9954 E-mail: *karen.clement@medtronic.com*

Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The Medtronic Model 6254, 6282, and 6293 Stylet Kits will allow separate packaging of lead stylets to be used with Medtronic transvenous leads. The Stylet Kits consist of three downsized knob stylets provided in 0.014 and 0.016-inch diameters. Each stylet kit will contain three stylets of the same diameter. The stylets are made of 304 stainless steel wire and have acetyl copolymer knobs. The stylets are inserted into a coiled polyethylene stylet ring for packaging and ease of use purposes.

Indications for Use

The stylet is intended to aid in the placement of Medtronic transvenous leads.

Substantially Equivalent Devices

The Medtronic Stylet kit Models 6254, 6282, and 6293 are believed to be substantially equivalent to the following predicate devices currently in interstate commerce with respect to comparable features, materials of construction and intended use.

- Accessory Stylet Kit Models 6505, 6506, 6507, 6508- Manufactured by Guidant (K9928663)
- Medtronic Stylet Kit Models 6282, 6293, and 6254 (K003535)

Labeling, packaging and sterilization of the Stylet Kit is substantially equivalent to that of the predicate devices listed above.

Summary of Studies

Medtronic, Inc. performed bench testing that included environmental conditioning package testing and lead compatibility to support Medtronic Stylet Kit Models 6254, 6282, and 6293 are equivalent to the predicate devices. All bench testing results for the Stylet Kit Models 6254, 6282, and 6293 met specified requirements.

Conclusion (Statement of Equivalence)

Through data and information presented, numerous similarities support a determination of substantial equivalence, and therefore market clearance of the Medtronic Stylet Kit Models 6254, 6282, and 6293 through this 510(k) Pre-Market Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2001

Ms. Karen Clement
Medtronic, Inc.
4000 Lexington Avenue North
Shoreview, MN 55126-2983

Re: K010906
Medtronic Stylet Kit Models 6282, 6293 and 6254
Regulatory Class: II (two)
Product Code: 74 DRB
Dated: March 23, 2001
Received: March 26, 2001

Dear Ms. Clement:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

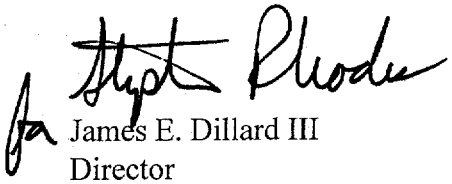
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K010906

Device Name: Stylet Kit Models 6254, 6282, and 6293

Indications For Use:

The stylet is intended to aid in the placement of Medtronic transvenous leads.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K010906

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)